

U.S.S.N. 10/083,413  
FILED: February 27, 2002  
AMENDMENT AND RESPONSE

### In the Claims

1. (currently amended) A solid, self-bioadhesive composition for topical application that adheres to oral mucosal tissue comprising:

(a) a therapeutically effective bioactive amount of at least one agent selected from the group of herbal and homeopathic active agent agents and drugs,

wherein the herbal and homeopathic agents are selected from the group consisting of bioactive herbs, herbal extracts, tinctures, essential oils, and mixtures thereof or an agent and the drugs are selected from the group consisting of analgesics, anti-inflammatories, antihistamines, antigens, steroids other than anti-inflammatories, antimicrobial drugs, vitamins, enzymes, antipyretics, antimalarial drugs, antiulcer drugs, peptides, and combinations thereof, wherein the agent is present in a homeopathic amount, which is less than a therapeutically effective amount; and

(b) a pharmaceutically acceptable solid bioadhesive carrier comprising a mucoadhesive synthetic polycarboxylic acid polymer in an amount from about 40 to 99 percent based on the weight of the whole composition in a form suitable for administration and adhesion to the oral mucosa.

2. (previously presented) The solid composition of claim 1 wherein the composition is in the form of a disc of 2 to 15 mm diameter and 0.4 to 2.3 mm thick that adheres to the oral mucosal tissue for at least 30 minutes.

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3. (previously presented) The solid composition of claim 1 where the composition is in the form of a disc 5 to 11 mm in diameter and 1 to 2 mm thick with tissues adherence of at least 1 hour.

4. (previously presented) The composition of claim 1 wherein the herbal active agent is selected from the group consisting of anti-inflammatory, analgesic, antiaching, anesthetic, antimicrobial, antifungal, antiseptic, antiviral, antibiotic, antiparasite agents, and combinations thereof.

5. (canceled)

6. (currently amended) The composition of claim 1 wherein the ~~herbal active agent or~~ and homeopathic ~~agent is agents~~ agents are selected from the group consisting of Echinacea, Salvia officinalis, Hypericum, Myrrh, Camphoria, Uncaria, menthol, Plantago, Baptisia, Calendula, Phytolacca, Catechu black, Coneflower, Krameria, Tsuga, grape fruit seed extract, Rosmarinus, Styrax, Crataegus, Glycerrhiza, Angelica, Krameria, Matricaria, Mallow, Propolis, Sage, berberine from hydrastis canadensis L., plant family Berberidaceae, gentian from the gentianaceae family of plants for the treatment of fungal infections, monoterpenes of three unsaturations, Taraxacum extract, Lonicera flower extract, Scutellaria root extract, Gardenia fruit extract, Pulsatilla root extract, Pueraria root extract, Radix gentianae Longdancao antifungal agent, and combinations thereof.

7. (previously presented) The composition of claim 1, wherein the herbal active agent is an essential oil selected from the group consisting of citronella oil, lemon oil, citron oil, pomelo

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peel oil, cedarwood oil, juniper berries oil, lemon basil oil, Rosmarinus officinalis oil, cinnamon oil, cajuput oil, eucalyptus oil, fennel oil, geranium oil, girofle oil, lavender oil, clove oil, spearmint oil, myrtle oil, oregano oil, pine oil, rosemary oil, sarriette oil, thyme oil, tea-tree oil, and combinations thereof.

8. (previously presented) The composition of claim 7, wherein the herbal active agent is an essential oil selected from the group consisting of cinnamon oil, tea-tree oil, citronella oil, and combinations thereof.

9. (previously presented) The composition of claim 6, wherein the herbal active agent comprises at least one monoterpene with three unsaturations.

10. (previously presented) The composition of claim 1, wherein the herbal active agent is an essential oil and the essential oil is a natural or synthetic mixture consisting of limonene and at least one myrcene,  $\alpha$ -pinene,  $\beta$ -pinene, and sabinene characterized in that at least 60% by weight of the mixture is limonene.

11. (previously presented) The composition of claim 9, wherein the monoterpene with three unsaturations is a citrus oil selected from the group consisting of lemon oil, pomelo oil, citron oil, and combinations thereof.

12. (previously presented) The composition of claim 1, further comprising a salt selected from the group consisting of  $MgBr_2$ , NaCl, KCl and mixtures thereof.

13. (canceled)

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14. (previously presented) The composition of claim 1 further comprising Carnallite or a salt of Carnallite.

15. (previously presented) The composition of claim 1, further comprising a non-herbal active agent.

16. (previously presented) The composition of claim 15, wherein the agent is selected from the group consisting of at least one base or acid-addition salt of procaine, lidocaine, prilocaine, mepivacaine, dyclonine, dibucaine, benzocaine, chlorprocaine, tetracaine, bupivacaine, and etidocaine.

17. (previously presented) The composition of claim 15, wherein the non-herbal active agent is selected from the group consisting of at least one base or acid-addition salt of dexamethasone, triamcinolone, hydrocortisone, amphotericine B, nystatin, itraconazole, chlorhexidine, quaternary ammonium salts, parabens, and dextranase enzymes.

18. (cancelled)

19. (previously presented) The composition of claim 1, wherein the active agent consists of a mixture of natural or synthetic monoterpenes with three unsaturations selected from the group consisting of limonene, myrcene, pinenes, sabinene, and terpinene.

20. (previously presented) The composition of claim 15 comprising a citron oil and Carnallite salt at a ratio between 1:10 and 1:1.

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21. (previously presented) The composition of claim 15 comprising a citron oil and Camallite salt at a ratio between 1:10 and 1:1 and a local anesthetic selected from the group consisting of lidocaine, benzocaine, and bupivacaine.

22. (currently amended) The composition of claim 1, wherein the solid bioadhesive carrier is selected from the group consisting of a ~~natural, semisynthetic or crosslinked~~ synthetic ~~polyhydric polymer, a polycarboxylic acid polymer and mixtures thereof.~~

23. (currently amended) The composition of claim 22 1 wherein the ~~polyhydric polymer~~ is a copolymer of one or more polymers selected from the group consisting of hydroxypropyl cellulose, hydroxypropyl methylcellulose, hydroxyethylcellulose, carboxymethyl cellulose, dextran, arabinogalactan, pullulan, guar-gum, hyaluronic acid, pectins, starch derivatives, acrylic acid polymers, polymer of acrylic acid esters, ~~acrylic acid copolymers~~, polymers of vinyl alcohols, alkoxy polymers, polyethylene oxide polymers, polyethers and combinations thereof.

24. (previously presented) The composition of claim 1 further comprising an excipient selected from the group consisting of fillers, tableting excipients, lubricants, enhancers, flavors, taste-masking agents, pH controlling compounds, dyes, stabilizers, enzyme inhibitors, and mixtures thereof.

25. (previously presented) The composition of claim 24 wherein the enhancers are selected from the group consisting of bile acids and limonene.

26. (currently amended) The composition of claim 22 wherein the solid bioadhesive carrier is selected from polyacrylic acid polymers ~~lightly~~ crosslinked with a polymer selected

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from the group consisting of polyalkenyl polyether, carboxymethylcellulose, hydroxymethylcellulose, and mixtures thereof.

Claims 27-37. (canceled)

38. (previously presented) The composition of claim 1, wherein the composition has a surface area ranging from about 0.4 to about 3 cm<sup>2</sup>.